DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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January 9,2015

Straumann USA, LLC
Jennifer M. Jackson M.S.
Senior Regulatory Affairs Project Manager
60 Minuteman Road
Andover, MA 01810

Re: K142890
Trade/Device Name: Straumann Variobase Abutment NNC, Straumann Variobase Abutment RN, Straumann Variobase Abutment WN, Straumann Variobase Abutment NC, Straumann Variobase Abutment RC, IPS e.max CAD MO Coping, IPS e.max CAD LT Crown, IPS e.max CAD HT Crown, coron CoCr Single Unit
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: December 22, 2014
Received: December 23, 2014

Dear Ms. Jackson,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Director, Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142890

Device Name
Straumann® Variobase™ Abutment NNC, Straumann® Variobase™ Abutment RN, Straumann® Variobase™ Abutment WN, Straumann® Variobase™ Abutment NC, Straumann® Variobase™ Abutment RC, IPS e.max® CAD MO Coping, IPS e.max® CAD LT Crown, IPS e.max® CAD HT Crown, coron CoCr Single Unit

Indications for Use *(Describe)*
The Straumann® Variobase™ Abutment is a titanium base placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann® Variobase™ Abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations. All digitally designed copings and/or crowns for use with the Straumann® Variobase™ Abutment system are intended to be sent to Straumann for manufacture at a validated milling center.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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5 510(k) Summary

5.1 Submitter's Contact Information

Straumann USA, LLC (on behalf of Institut Straumann AG)

60 Minuteman Road

Andover, MA 01810

Phone Number: 1-978-747-2509

Fax Number: 1-978-747-0023

Contact Person: Jennifer M. Jackson, MS

Date of Submission: January 8, 2015

5.2 Name of the Device

Trade Name: Straumann® Variobase™ Abutment NNC, Straumann® Variobase™ Abutment RN, Straumann® Variobase™ Abutment WN, Straumann® Variobase™ Abutment NC, Straumann® Variobase™ Abutment RC, IPS e.max® CAD MO Coping, IPS e.max® CAD LT Crown, IPS e.max® CAD HT Crown, coron CoCr Single Unit

Common Name: Dental Implant Abutment

Classification Name: Abutment, Implant, Dental, Endosseous

Regulation Number: §872.3630

5.3 Predicate Device(s)

- K120822, Straumann CARES Variobase Abutment NNC, RN, WN, NC, RC (Institut Straumann AG)
- K120053, IPS e.max® Press – Abutment Solutions (Ivoclar Vivadent AG)
- K132209, IPS e.max® CAD Abutment Solutions (Ivoclar Vivadent AG)
- K132219, Straumann Variobase Abutments

5.4 Device Description

The Straumann® Variobase™ Abutments are pre-manufactured (stock) abutments, sometimes referred to as “Ti-bases”. Straumann® Variobase™ Abutments are available to fit Straumann® dental implant platforms NNC (Narrow Neck CrossFit®), RN (Regular Neck), WN (Wide Neck), NC (Narrow CrossFit®), and RC (Regular CrossFit®). A dental laboratory technician would design the corresponding coping and/or crown (the second component of the Variobase two-piece abutment) and/or prosthetic restoration in the dental laboratory via their preferred workflow for pressing, casting, or milling using either a burnout coping or STL model for open CAD software. The coping and/or crown would be manufactured via traditional laboratory methods for pressing or casting, or via validated Straumann milling.

The purpose of this submission is to add coping and/or crown materials to the Straumann® Variobase™ Abutment portfolio for the previously cleared validated Straumann milling workflow and to expand the design/manufacturing workflow to include in-lab pressing and casting techniques and materials.

5.5 Intended Use

The Straumann® Variobase™ Abutment is a titanium base placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann® Variobase™ Abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations.

5.6 Indications for Use

The Straumann® Variobase™ Abutment is a titanium base placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann® Variobase™ Abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations. All digitally designed copings and/or crowns for use with the Straumann® Variobase™ Abutment system are intended to be sent to Straumann for manufacture at a validated milling center.

5.7 Technological Characteristics

Straumann® Variobase™ Abutments are two-piece abutments consisting of a pre-manufactured (stock) abutment made from a titanium-aluminum-niobium alloy and a coping and/or crown which is designed in the dental laboratory by a dental technician and manufactured via traditional in-lab methods of pressing or casting, or via validated Straumann milling.

The Ti-base components of the Straumann® Variobase™ Abutments are identical to the Ti-base components of the Straumann predicates (K120822 and K132219). The CAD and press materials which may be used to manufacture the coping/crown component of the Straumann Variobase Abutments are identical to the identified predicate devices and include:

Casting:	Type 4 metals (ISO 22674)
	Base metal alloy (e.g., cobalt-chromium (CoCr))
	Noble metal alloy (e.g., gold alloy)
Pressing:	IPS e.max® Press Ceramic (K120053)
CAD:	IPS e.max® CAD Ceramic (K132209)
	coron®

5.8 Performance Testing

The material used in the manufacture of Straumann® Variobase™ Abutments is a titanium-aluminum-niobium alloy which meets the requirements of ISO 5832-11. Bench testing was performed with each coping/crown material to evaluate the performance of the proposed Straumann® Variobase™ Abutments. Dynamic fatigue tests were conducted in according to the FDA guidance document *"Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments"*.

5.9 Conclusion

The documentation submitted in this premarket notification demonstrates that the Straumann® Variobase™ Abutments are substantially equivalent to the predicate devices and do not pose new issues of safety and effectiveness when used as labeled.